

DELEGATIONS OF AUTHORITY
Issue Certificates of Confidentiality Under Section 301(d) of the PHS Act

Authority Delegated

To issue Certificates of Confidentiality under section 301(d) of the Public Health Service (PHS) Act, as amended (42 U.S.C. 241(d)), in order to protect the identity of research subjects.

<u>To Whom Delegated</u>	<u>Area of Authority</u>
Deputy Director, NIH	NIH
Deputy Director for Intramural Research	NIH
Deputy Director for Extramural Research	NIH
IC Directors	NIH

Existing delegations under section 301 of the PHS Act, as amended, provide authority to grant this protection. Accordingly, NIH Manual 1130, Delegations of Authority, [Program: General Nos. 18, "PHS Act, Title III"](#) and [18A, "PHS Act, Section 301"](#) are amended consistent with the information contained in this delegation. Other NIH delegations of authority inconsistent with the provisions of this delegation are hereby superseded.

Limitations/Guidance

1. This authority shall be exercised in accordance with the memorandum from the Assistant Secretary for Health, dated January 2, 1997, to HHS OPDIVs, entitled: Protection of Identity of Research Subjects -- Section 301(d) of the Public Health Service Act -- Locus of Administration.
2. Certificates of Confidentiality are issued, upon application, to persons engaged in biomedical, behavioral, clinical, or other research for a particular project to protect the privacy of subjects in health research projects against compulsory legal demands, e.g., court orders and subpoenas, that seek the names or other identifying characteristics of the research subjects. Federal funding is not a prerequisite.

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3. Officials delegated authority to issue Certificates of Confidentiality hereunder may grant this protection NIH-wide.
4. The Deputy Director for Extramural Research is authorized to coordinate and issue policies for the administration of the authority to issue Certificates of Confidentiality. This includes the authority to establish one or more service centers in cooperation with the IC that will operate the center. IC use of any service center is discretionary.

Redelegation

This authority may be redelegated to IC Deputy Directors and Executive Officers. No further redelegation is permitted.

Citations

1. 5 U.S.C. 302; 42 U.S.C. 203, 216, 241(d), and 282.
2. Memorandum to OPDIV Heads from the Assistant Secretary for Health, dated January 2, 1997, entitled: Protection of Identity of Research Subjects -- Section 301(d) of the Public Health Service Act -- Locus of Administration.
3. Memorandum to the Director, NIH, from the Assistant Secretary for Health, dated June 26, 1981, entitled: Delegation of Authority Under Title III of the PHS Act, as Amended.

/s/
Ruth L. Kirschstein, M.D.
Acting Director, NIH

Effective Date: April 12, 2002